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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,429	08/07/2006	Norihiro Nishimoto	053466-0417	6508

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,429	NISHIMOTO ET AL.	
	Examiner	Art Unit	
	Lorraine Spector	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-42* is/are pending in the application.

4a) Of the above claim(s) *16,18,19,23,26,30,32,33,37 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,17,21,22,24,25,27-29,31,34-36,38,39,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/06, 11/20/07, 6/4/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species polyarteritis nodosa in the reply filed on 1/22/09 is acknowledged.

Claims 15, 17, 21-22, 24, 25, 27-29, 31, 34-36, 38, 39, 41 and 42 are under consideration. Applicants erroneously omittetd claims 29 as an elected claim, and included claim 30, which is not elected. Applicants are advised to amend the claim status identifiers accordingly when responding to this Office Action.

Objections

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Specifically, the title should make mention of inhibition of IL-6.

Claim Rejections - 35 USC § 112

Claims 15, 17, 21-22, 24, 25, 27-29, 31, 34-36, 38, 39, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite prevention of vasculitis. However, it is not recognized in the art that vasculitis can be prevented, and there is no guidance in the specification of how to identify a patient in need of such treatment, nor how to administer such treatment. Accordingly, the specification does not provide enablement for prevention of vasculitis.

The prevention of vasculitis would require knowledge of who is likely to develop vasculitis, and when and how to administer the medication to prevent such. The specification provides no guidance on any of these issues. All that is presented is a mere wish to prevent vasculitis.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of Genentec, Inc, v. Novo Nordisk, 42 USPQ 2d 100,(CAFC 1997), the court held that:
"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot, following the guidance presented therein, practice the suggested method without first making a substantial inventive contribution.

Claims 25, 28, 39 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The practice of the claims requires the availability of the PM-1 antibody. It is noted that the specficiation discloses:

> [0061] Incidentally, the hybridoma cell line which produces PM-1 antibody has been internationally deposited under the provisions of the Budapest Treaty as PM-1 on Jul. 12, 1995 with the Patent Microorganism Depository of the National Institute of Industrial Science and Technology, at Chuo 6, 1-1, Higashi 1-chome, Tsukuba city, Ibaraki pref., Japan, as FERM BP-2998. The hybridoma cell line which produces MR16-1 antibody has been internationally deposited under the provisions of the Budapest Treaty as MR16-1 on Mar. 13, 1997 with the Patent Microorganism Depository of the National Institute of Industrial Science and Technology, at Chuo 6, 1-1, Higashi 1-chome, Tsukuba city, Ibaraki pref., Japan, as FERM BP-5875.

If a deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R.§1.808. That statement has not been made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

U.S. Patent No. 5,817,790, cited by applicants.

The '790 patent discloses antibody PM-1, which is an antibody against the human IL-6 receptor, hybridomas producing such, and the production of humanized versions of the antibody; see column 44, and claims. At column 21, it is disclosed that the antibodies are useful for the preparation of pharmaceutical compositions. The person of ordinary skill in the art is fully aware that an excipient, as applied to a pharmaceutical composition is a substance that acts as a vehicle for the drug. Therefore, the mere mention of "pharmaceutical composition" comprising an antibody would suggest to the person of ordinary skill in the art that an excipient *must* be present, as it is not routine in the art to administer crystallized antibodies (antibodies are generally administered intravenously. The recitation that the agent is intended to treat vasculitis, particularly polyarteritis nodosa, is given weight only to the extent that the product must be *usable* for such; the reference does not have to teach that particular use.

With respect to claim 29, since the claims encompass prevention, any administration would inherently result in such; the patent teaches several pharamaceutical uses for the antibody. Accordingly, the claims are anticipated.

Claims 15, 17, 20-22, 24, 25, 27-29, 31, 34-36, 38, 39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,888,510.

The '510 patent discloses production of monoclonal antibody PM-1, an antibody against human IL-6 receptor; see columns 9-10. Pharmaceutical compositions comprising such antibodies are claimed, for example see claims 1, 2 and 8-9. Human antibodies are disclosed at the bottom of column 3. Chimeric and humanized ("reshaped") antibodies are disclosed at column 6, and are recombinantly produce.

The recitation in the pending claims that the agent is intended to treat vasculitis, particularly polyarteritis nodosa, is given weight only to the extent that the product must be *usable* for such; the reference does not have to teach that particular use.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 29 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,888,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented

claims are all drawn to administration of an IL-6 antagonist for the inhibition of synovial cell growth. As explained above, since the claims encompass prevention, any administration would inherently result in such. Accordingly, the claim is anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday from 9-5, and Tuesday, Thursday and Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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